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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/058,597 | 01/28/2002 | Sanjay Kapil | 30921-CIP1 | 4069 |
| 23589 | 7590 | 12/03/2003 | EXAMINER | |
| HOVEY WILLIAMS LLP 2405 GRAND BLVD., SUITE 400 KANSAS CITY, MO 64108 | | | TUNG, JOYCE | |
| | | | ART UNIT | PAPER NUMBER |

1637

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/058,597 | KAPIL ET AL. | |
| | Examiner | Art Unit | |
| | Joyce Tung | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-128 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-128 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28, drawn to a method of ascertaining the susceptibility to PRRS infection in an animal, classified in class 435, subclass 6.
 - II. Claims 29-43, drawn to a method of preparing PRRSV vaccine stock, classified in class 424, subclass 184.1.
 - III. Claims 44-54 and 59-61, drawn to a transformed cell line containing DNA coding for CD 151 and an isolated DNA sequence having at least about 91% sequence homology with SEQ ID NO:1 and a vector containing SEQ ID NO: 1, classified in class 536, subclass 22.1.
 - IV. Claims 54-58, 62-65 and 120-123, drawn to a plasmid, a vector containing a DNA sequence at least 84% sequence homology with SEQ ID NO:14, and isolated DNA sequence coding for CD 151 having at least 84% sequence homology with SEQ ID NO:14, classified in class 536, subclass 22.1.
 - V. Claims 66-77, drawn to a method of rendering a cell line susceptible to PRRSV infection, classified in class 435, subclass 325.
 - VI. Claims 78-84, drawn to a method of selecting animals for breeding comprising the steps of screening a sample of cellular material from said animals for the presence of CD 151 to obtain a CD 151 level, classified in class 435, subclass 6.

- VII. Claims 85-89, drawn to a method of modifying PRRSV production in cells, classified in class 424, subclass 204.1.
- VIII. Claims 90-96, drawn to a method of blocking entry of PRRSV, classified in class 424, subclass 9.51.
- IX. Claims 97-103, drawn to a method of diagnosing PRRSV infection, classified in class 424, subclass 9.1.
- X. Claims 104-113, drawn to a method of integrating CD 151 coding sequences directly into a chromosome, classified in class 435, subclass 252.3.
- XI. Claims 114, drawn to a modified genome expression, classified in class 435, subclass 70.1.
- XII. Claims 115, drawn to an animal having a modified genome, classified in class 800, subclass 13.
- XIII. Claims 116-119, drawn to an isolated mRNA having at least 84% sequence homology with SEQ ID NO: 38, classified in class 536, subclass 22.1.
- XIV. Claims 124-128, drawn to an isolated DNA coding for CD 151 comprising a sequence selected from the group consisting of SEQ ID NO: 15-29, classified in class 536, subclass 22.1
- XV. Claims 129-131, drawn to a vaccine for inducing effective immunity against PRRSV, classified in class 514, subclass 2.
- XVI. Claims 132, drawn to a method of determining the effect of single nucleotide polymorphisms on PRRSV susceptibility, classified in class 435, subclass 6.

- XVII. Claims 133-135, drawn to a method of modulating viral RNA entry into cells comprising the step of altering the amount of CD 151 of said cells. classified in class 435, subclass 6.
- XVIII. Claims 136, drawn to a method of comparing PRRSV susceptibility factors between individual swines, classified in class 435, subclass 6/7.1.
- XIX. Claims 136-138, drawn to a method of determining CD151 sequences of swine by performing PCR on a biopsy from a swine, classified in class 435, subclass 91.2.
2. The inventions are distinct, each from the other because of the following reasons:
- a. Inventions III-IV, XI-XIV, XV and I-II, V-X and XVI-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product group III is drawn to a transformed cell line which can be used in recombinant DNA, group IV is drawn to a plasmid which can be used in recombinant DNA, group XI is drawn to a modified genome expression which can be used to produce an altered protein, group XII is drawn to an animal having modified gene which can be used in studying various diseases, group XIII and XIV is drawn to an isolated mRNA and DNA which can be used in nucleic acid purification and group XV is drawn to a vaccine for inducing effective immunity against PRRSV which can be used for preventing PRRSV.

b. Among groups I-II, V-X and XVI-XIX, these inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these groups are different inventions because they have different methods steps and different functions. Group I is drawn to a method of ascertaining the susceptibility to PRRS infection involving polymerase chain reaction, Group II is drawn to a method of preparing PRRS vaccine stock involving producing antibody to the viruses, Group V is drawn to a method of rendering a cell line, Group VI is drawn a method of selecting animal involving the steps of selecting animal, Group VII is drawn to a method of modifying PRRSV production cells, Group VIII is drawn to a method of blocking entry of PRRSV comprising the step of blocking PRRSV RNA from interaction with CD 151, Group IX is drawn to a method of diagnosing PRRSV infection involving in vitro diagnostic test, Group X is drawn to a method of integrating CD 151 coding sequences into a chromosome involving the step of contacting a chromosome with vector, Group XVI is drawn to a method of determining the effect of single nucleotide polymorphisms on PRRSV susceptibility comprising comparing single nucleotide polymorphisms between two CD 151 genomic sequences and correlating the single nucleotide polymorphisms with susceptibility to PRRSV, Group XVII is drawn to a method of modulating viral RNA entry into cells comprising the step of altering the amount of CD 151 of said cells, Group XVIII is drawn to a method of comparing PRRSV susceptibility factors between individual swines comprising the steps of obtaining the genetic sequence of at least two swines, analyzing the amount of CD151 encoding

sequence and comparing the amount of CD151 encoding sequence and Group XIX is drawn to a method of determining CD151 sequences of swine by performing PCR on a biopsy from a swine. Based upon the analysis above, these inventions have different method steps. Thus, they are distinct inventions.

c. Among the product groups, Group III is drawn to a transformed cell line which has different sequence from Group IV which is drawn to a plasmid having SEQ ID NO:14. Group XI is drawn to a modified gene expression of an altered level of CD 151, Group XII is drawn to an transgenic animal, Group XIII is drawn to an isolated mRNA having SEQ ID NO:38 and Group XIV is drawn to an isolated DNA selected from the group consisting of SEQ ID NO: 15-29 and Group XV is drawn to a vaccine for inducing effective immunity against PRRSV in which the vaccine comprises viral progeny produced in a non-simian cell line transformed with non-simian CD 151. Since these groups are drawn to different components as set forth above, they are different inventions.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. These claims are generic to a plurality of disclosed patentably distinct restriction groups comprising different SEQ ID NOs. Applicant is required under 35 U.S.C. 121 to elect no more than 1 disclosed nucleic acids even though this requirement is traversed.

Should applicant traverse on the ground that some or all of the different nucleic acids are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the nucleic acids to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. A telephone call was made to Mr. Tracey Truitt on 10/28/2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703 (305) 3014.


8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 (308) 0196.

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Art Unit: 1637

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Joyce Tung

November 17, 2003


ETHAN WHISENANT
PRIMARY EXAMINER